REMARKS

Claims 2, 5, 7, 11, 15-16, 18-19, 31, 34-35, and 56-59 are pending in this application. Claims 4, 9, 42, 46, 112, 114-115, 118, 120-121, and 124 125 have been cancelled. Each claim amendment is supported in the specification. No new matter has been added to the present application.

Specification

Applicants have amended the specification as suggested by the Examiner in order to address concerns regarding the amendment to the first line of the specification which included an incorporation by reference of the 09/881,797 application. Reconsideration and withdrawal of this objection to the specification are respectfully requested.

35 U.S.C. §112, first paragraph Claim Rejections

Claims 2, 4-5, 7, 9, 11, 15-16, 18-19, 31, 34-35, 42, 46, 56-59, 112, 114-115, 118, 120-121, and 125 stand rejected under 35 U.S.C. §112, first paragraph, because the Examiner alleges that the specification does not enable one skilled in the art to use the invention commensurate in scope with the claims. Applicants respectfully traverse the Examiner's contention.

Independent claims 2 and 5 have been amended to delete the phrases containing the articles "a" or "an." Specifically the phrases "an amino acid sequence set forth in" and "a nucleotide sequence as set forth in" have been deleted so that the claims recite "an isolated nucleic acid encoding a polypeptide comprising SEQ ID NO:111 . . ." and "an isolated nucleic acid comprising SEQ ID NO.:19 . . ." Applicants acknowledge that the specification is enabling for an isolated nucleic acid set forth as SEQ ID NO:19 with the exception that the nucleotide sequence contains a single nucleotide polymorphism of guanine to adenine at position 21 of SEQ ID NO: 5969 or encoding a polypeptide comprising SEQ ID NO:111 with the corresponding amino acid change, and vectors and isolated host cells comprising said nucleic acid. Therefore, in view of the presently amended claims, applicants respectfully request reconsideration and withdrawal of this §112, first paragraph rejection.

Claims 31, 34, and 35 stand rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the enablement requirement since, according to the Examiner, the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully traverse this rejection.

The Examiner focuses his arguments on the use of the claimed pharmaceutical compositions for gene therapy, but the pharmaceutical compositions are not limited to this use. In fact, there are several disclosed uses for the claimed pharmaceutical compositions.

The Examiner states that the examples of alternative uses cited by the applicants are not therapeutic applications and therefore would not meet the definition of a pharmaceutical use because the "Office construes a composition specifically limited to being a 'pharmaceutical' as a composition intended for pharmaceutical use." (Office Action, page 13, lines 3-6). Applicants respectfully disagree, as the term "pharmaceutical" does not limit the claims to therapeutic use only. In fact, as defined by Merriam-Webster, "pharmaceutical" refers to a medicinal drug (Merriam-Webster Online Dictionary, 2006). One skilled in the art would be likely to consult a more technical dictionary, such as Dorland's Illustrated Medical Dictionary (online, 2006), which defines "pharmaceutical" as pertaining to pharmacy or drugs. A drug is any substance, other than food, used in the prevention, diagnosis, alleviation, treatment, or cure of disease. As one skilled in the art understands, drugs may be used in research and medicine for a myriad of uses not limited to therapeutic uses, including, for example, assays, diagnostics, drug screening, etc. It is clear, therefore, that pharmaceutical compositions are not limited to use in therapeutics.

Since a pharmaceutical composition need not be limited to a therapeutic use, applicants assert that the claimed pharmaceutical compositions have *multiple* uses in addition to gene therapy. The pharmaceutical compositions are useful in diagnostic assays for identifying specific genes, diagnosing diseases and predispositions for said diseases, identifying abnormalities and mutations, and drug screening, evaluation, and discovery. For example, applicants direct the Examiner's attention to the instant specification, page 2, line 29 through page 3, line 10 which discloses the use of the claimed nucleic acids for assaying biological samples for the presence of 12q23-qter genes, and to page 81, line 10- page 82, line 27 which discloses examples of specific methodologies for using the claimed nucleic acids for assaying

biological samples for the presence of 12q23-qter genes. Applicants further direct the Examiner's attention to page 3, lines 11-22 and page 82, line 28- page 83, line 24, disclosing that the claimed nucleic acids may be used for diagnosing diseases and examples of methodologies for diagnosing diseases, as well as determining the predisposition of a subject for having such a disease; at page 4, line 23 through page 5, line 2, the claimed nucleic acids may be used to identify chromosomal abnormalities and allelic variants/ mutations; at page 87, line 28 through page 88, line 3, the claimed invention may be used for drug screening; and at page 106, lines 6-16, transgenic animals containing a nucleic acid molecule which encodes a human 12q23-qter polypeptide may be produced for use in drug evaluation and drug discovery. Applicants have clearly demonstrated throughout the instant specification, various uses for the pharmaceutical compositions including assays, diagnostics, drug screening, and gene therapy.

Furthermore, the basis of this rejection is not applicable to the rejection of claims 31, 34, and 35 because the pharmaceutical composition of claims 31, 34, and 35 are not limited to one recited use. As a reminder, applicants respectfully direct the Examiner's attention to MPEP 2164.01(c), middle of the last paragraph, which reads, "[i]f multiple uses for claimed compounds or compositions are disclosed in the application, then an enablement rejection must include an explanation, sufficiently supported by the evidence, why the specification fails to enable each disclosed use. In other words, if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention" (emphasis added). As the pharmaceutical composition of claims 31, 34, and 35 have multiple enabled uses in addition to gene therapy, applicants respectfully request reconsideration and withdrawal of the §112, first paragraph rejections.

In addition, the instant specification *does* provide guidance and teaching for the skilled practitioner to know how to administer the claimed pharmaceutical compositions of the invention for use in gene therapy. Applicants direct the Examiner's attention to page 43, line 21-page 44, line 5, in which delivery of nucleotide sequences to organs, tissues, and cells is disclosed, and to page 96, line 26-page 101 line 29, which describes gene therapy methodologies. Robbins (ed), 1997, *Gene Therapy Protocols,* Mackett et al., 1992, *Biotechnology*, **24**:495- 499, and Madzak et al., 1992, *J. Gen. Virol.*, **73**:1533-1536 are examples of cited references that describe methods for introducing DNA into cells, and viral and non-viral methods for gene transfer, with respect to gene therapy.

Regarding the Examiner's concern of what patient population to treat with the claimed pharmaceutical compositions, the instant specification clearly discloses patient populations in numerous instances as including those, for example, with obesity, inflammatory bowel disease, and lung disease, including asthma; applicants direct the Examiner's attention to page 2, lines 4-24, and to page 101, lines 26-29, which state that asthma has been linked to markers on human chromosome 12, that chromosomal region 12q23-qter has been associated with obesity, lung disease, and particularly, inflammatory lung disease phenotypes, and that the introduced gene products can be utilized to treat or ameliorate disorders such as asthma, obesity, or inflammatory bowel disease, that is related to altered levels of the 12q23-qter polypeptide.

Thus, it is respectfully asserted that the complete teachings of the specification, including the publications and general texts referred to in the specification (see above) combined with the level of knowledge possessed by those having skill in the art to which the invention pertains, allows the practice of the invention as claimed without undue experimentation.

Therefore, it is respectfully submitted that the instant specification clearly supports the pending claims, including the claims as amended and presented herein. Applicants respectfully request reconsideration and withdrawal of the §112, first paragraph rejection of claims 31, 34, and 35.

35 U.S.C. §112, second paragraph Claim Rejections

Applicants thank the Examiner for the withdrawal of the rejection of Claims 2, 4-5, 7, 9, 11, 15-16, 18-19, 31, 34-35, 42, 46, 56-59, 112, 114-115, 118, 120-121, and 125 based on 35 U.S.C. §112, second paragraph.

35 U.S.C. §§102(b) and 103 Claim Rejections

Applicants thank the Examiner for the withdrawal of the rejection of Claims 2, 4-5, 7, 9, 11, 15-16, 18-19, 42, 46, 56-59, 112, 114-115, 118, 120-121, and 125 based on 35 U.S.C. §102(b) as anticipated by Buell et al. and the rejection of Claims 31 and 34-35 based on §103 as obvious in view of Buell et al. and Maniatis et al.

35 U.S.C. §112, second paragraph Claim Rejections – New Grounds

Claim 34 is rejected under 35 U.S.C. 112, second paragraph as being indefinite. The Office Action indicates that the claim is missing essential elements in that it presently depends from a cancelled claim 14. Applicants have amended claim 34 (as well as claim 18) to depend from currently pending claim 15. Reconsideration and withdrawal of this §112, second paragraph rejection is respectfully requested.

35 U.S.C. §102(e) Claim Rejections – New Grounds

Claims 2, 4, 5, 7, 9, 11, 15, 16, 18, 19, 42, 46, 56-59, 112, 114, 115, 118, 120, 121, 124 and 125 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Buell et al. The Office Action indicated that because the indefinite article is used in referring to the disclosed sequence in the base claims, the claims can reasonable be construed as encompassing any nucleotide encoding or comprising any fragment of the disclosed sequence. Office Action at 20.

Claims 4, 9, 42, 46, 112, 114, 115, 118, 120, 121, 124 and 125 have been cancelled; hence, the rejection of these claims is moot. Applicants have amended the base claims, claims 2 and 5, to delete the phrases containing the indefinite articles "a" or "an." Specifically the phrases "an amino acid sequence set forth in" and "a nucleotide sequence as set forth in" have been deleted so that the claims recite "an isolated nucleic acid encoding a polypeptide comprising SEQ ID NO:111 . . ." and "an isolated nucleic acid comprising SEQ ID NO.:19 . . ." In addition, applicants have cancelled claims making the rejection with respect to these claims moot.

It is submitted that the cited prior art patent does not contain each and every element of applicants' reagent compositions as presently claimed. As stated in the previous response, the nucleic acid sequence of Buell encoding a polypeptide is only 99.3% identical to the instant SEQ ID NO: 111, and the Examiner further states that from nucleotide 48-1896, there is only 99.5% identity. However, when considering the full length sequence (our SEQ ID NO: 19), only 36% is identical to the nucleic acid sequence pointed out by the Examiner in Buell. More specifically, only 1837 bases of the 5087 bases of our SEQ ID NO: 19 are identical to that of Buell. For the same reason, the polypeptide of Buell is not identical to SEQ ID NO: 111. These sequences are not identical to that set forth in the nucleic acid sequence encoding SEQ ID

NO: 111 or SEQ ID NO: 19, having a single nucleotide polymorphism of guanine to adenine at position 21 of SEQ ID NO: 5969.

As the Examiner is aware, a reference that merely contains substantially the same elements is insufficient to anticipate the claimed invention. In fact, applicants respectfully submit that in order to anticipate a claim, the reference must teach each and every element of the claim (see MPEP 2103). The cited prior art fails to disclose the exact nucleic acid sequence as claimed and described in the instant specification.

Once again, since each and every base of a nucleic acid sequence needs to be correct, and the Buell publication reports of a sequence having only 99.3 % identity to the claimed sequence (i.e., not every base is identical), the Buell publication does not anticipate the instant claims. The claims of the instant invention are therefore not anticipated by the Buell, et al. publication of nucleic acids, vectors, host cells, kits and compositions. Thus, for the above-mentioned reasons, applicants respectfully submit that claims 2, 5, 7, 11, 15, 16, 18, 19, 46, and 56-59 are not anticipated by Buell, et al.

Therefore, reconsideration and withdrawal of this §102(e) rejection is respectfully requested.

35 U.S.C. §103 Claim Rejections

Claims 2, 4, 5, 9, 11, 15, 31, 34 and 35 are rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Buell et al., as applied to claims 2, 4, 5, 9, 11 and 15, in view of Maniatis et al. (Office Action at page 21).

It is respectfully submitted that some of the claims rejected by the Examiner are not currently pending in the application, *i.e.*, claims 4 and 9 have been cancelled, and the rejections to these claims are thereby moot. Independent claims 2 and 5 have been amended, and accordingly, depending claims 11, 15, 31, 34, and 35 also incorporate these amendments. As described above, the nucleic acid reported in Buell, et al. is not what is claimed in the pharmaceutical composition of the instant invention. As the primary reference (i.e. Buell) does not teach the nucleic acid sequence of SEQ ID NO: 19 with the exception that the nucleotide sequence contains a single nucleotide polymorphism of guanine to adenine at position 21 of SEQ ID NO: 5969, the vector and the pharmaceutical composition comprising the claimed nucleic acid sequences are therefore not obvious in view of Buell. The has combined the Buell reference

with the Maniatis reference to allege the claims directed to pharmaceutical compositions with the nucleic acid of interest (*i.e.*, claims 31, 34 and 35) is obvious. However, the Buell reference does not teach or suggest the claimed invention even with the Maniatis reference. Maniatis is a general technical reference that discloses suitable carriers, excipients, and diluents. Buell, et al. does not describe the nucleic acid as presently claimed regardless of the carrier or buffer of Maniatis, et al. Therefore, the deficiencies of Buell are not overcome with Maniatis. Thus, applicants respectfully request reconsideration and withdrawal of this §103 rejection.

CONCLUSION

Based on the foregoing amendments and remarks, applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 2976-4044US1. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 2976-4044US1. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,
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with the Maniatis reference to allege the claims directed to pharmaceutical compositions with the nucleic acid of interest (*i.e.*, claims 31, 34 and 35) is obvious. However, the Buell reference does not teach or suggest the claimed invention even with the Maniatis reference. Maniatis is a general technical reference that discloses suitable carriers, excipients, and diluents. Buell, et al. does not describe the nucleic acid as presently claimed regardless of the carrier or buffer of Maniatis, et al. Therefore, the deficiencies of Buell are not overcome with Maniatis. Thus, applicants respectfully request reconsideration and withdrawal of this §103 rejection.

CONCLUSION

Based on the foregoing amendments and remarks, applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 2976-4044US1. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 2976-4044US1. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

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